

RESEARCH PROTECTIONS UPDATE

News and Comment on the Protection of Human Subjects in Navy and Marine Corps Research

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Comment

In Pursuit of the Mission

The Department of the Navy Human Research Protection Program (DON HRPP) has in recent months gone through a remarkable series of changes in leadership, staffing, and in the scope of the program. As reported in our last issue, CAPT William Deniston has taken the helm as director. That news followed the announcement of CDR Katie Shobe coming aboard as deputy at the Office of Naval Research (ONR), Research Protections Division.

This issue reports four more ONR staff changes: Terrence Clemmons taking over as Human Research Protections Administrator and Acting Director of the Research Protections Division, Tamika Brown as Human Research Protection Specialist (Training), Adrienne Campbell of Avian LLC as Human Research Compliance Specialist and Suzanne May as Human Research Protection Specialist.

This issue also features stories, starting on pages 3 and 5, on the mission and work of a little-known community—the (now) 11 Navy nurse researchers assigned to Naval Medical Center Portsmouth (NMCP) and San Diego (NMCS), Uniformed Services University of the Health Sciences (USUHS), and the National Capital region.

Their numbers are increasing as more Navy nurses complete advanced education and training. They are

pursuing dynamic research in areas of critical relevance to the Services today: combat casualty care, Post Traumatic Stress Disorder (PTSD), mild and severe traumatic brain injury, and the impact of those conditions on families.

As these stories report, the Navy's nursing research programs are deeply sensitive to the protection of human subjects in their work.

That sensitivity is demonstrated increasingly throughout the Navy's research community.

At DON HRPP, we see greater attention devoted to human research protection needs, long-accepted in medical research, also on the fleet-operational side.

The Navy is pursuing groundbreaking work in addressing such critical areas as noise-induced hearing loss, development of human-machine interfaces for shipboard and airborne weapons, sensors, and cockpit systems, surface-warfare training, and wargaming.

In the larger domain of strategy, important work is underway, in response to the Department of Defense (DoD) Minerva initiative. This research explores such social-cultural-political trends as the inclination to radicalization in unstable regions, which may affect U.S. foreign and defense policies. Such work typically is carried out by extramural (non-government) inst-

itutions: contractors, colleges, and universities, which must obtain not only a Federalwide Assurance (FWA) from the Office of Human Research Protections of Health and Human Services, but also the DON's Addendum to the FWA, which mandates compliance with unique DON and DoD standards.

All of this translates to a decisive truth: protection of human subjects is a fully accepted component of DON research.

In recent months our compliance specialists have returned from site inspections and assist visits to report that DON Commands have achieved impressive progress with their programs: they are conscientious and highly effective in training staff members, meticulous in record-keeping, and forthright and thorough in communicating requirements and challenges with Command and DON HRPP leadership.

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Navy Nursing Research: Small Wonder

By CAPT William Deniston

The Naval Medical Centers at Portsmouth (NMCP) and San Diego (NMCSO) represent many unique components of Navy medicine, in the dedication of their staffs, sterling quality of care, and responsiveness to deployed operating units and to Navy/Marine Corps families.

They also are the primary showcases for the Navy's nursing research program. This issue of *Research Protections Update* reports on both the Portsmouth and San Diego programs, with perspective from CDRs Craig Cunningham, head of Nursing Research & Consultation Services at Portsmouth and Dennis Spence, Regional Director of Nursing Research, Navy Medicine West (NAVMEDWEST).

As both officers report, their programs are going through important and decisive changes that will enhance their contributions to the Fleet/Force.

Navy nursing research, as CDR Cunningham points out, is a relatively small community in Navy medicine, with only 11 billets, three each at Portsmouth and San Diego; the others scattered among the National Capital Area, USUHS, and elsewhere. Both NMCP and NMCSO seek to select the best and the brightest among Navy nurses for further training and education to the Ph.D. level, equipping them for important roles in research both at the NMCs

and when deployed.

The research is anything but academic. CDR Spence describes work now underway by CDR Heather King, an NMCSO nurse researcher aboard the hospital ship *Mercy* this summer, to produce an oral history of commentary by Navy medical staff members who have served on humanitarian and disaster-assistance missions. The history will serve as an important training tool for staff members on future operations.

CDR Cunningham stresses the central importance of training the nurse researchers in human research protections. Portsmouth's Nursing Research and Standards Committee, he says, as it works to attract nurses to research, provides extensive exposure to HRPP policies and practices: research ethics, the Institutional Review Board (IRB) process, informed consent, across the full range of requirements for protecting research subjects.

As at San Diego, nurse researchers at Portsmouth are engaged in original and important studies including work on PTSD, traumatic brain injury, post-operative pain, and many others. They are a small community, but one that boasts an impact on Navy research far beyond its numbers.

New Role for Clemmons; Brown, Campbell, and May Come Aboard at ONR

Terrence Clemmons has been named acting director of the Research Protections Division at the Office of Naval Research (ONR 343). The Chief of Naval



Terrence Clemmons

Research (CNR), by way of ONR 343, provides support and expertise to the Navy Surgeon General (SG) and DON HRPP for human

research protection in the DON's Systems Commands, operational forces, training commands, and non-DoD institutions that conduct DON-supported research involving human subjects. CNR stood up the Research Protections Division in August 2005.

Clemmons had been the Human Research Protection Administrator within ONR 343 where he served as the DON HRPP point of contact for the Naval Sea Systems Command as well as for NAVSEA labs at Dahlgren, Va., and Carderock, Md., and the U.S. Marine Corps. Clemmons came to DON HRPP's ONR office in 2007 from the

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Navy Nursing Research, Portsmouth

NMCP's Navy Nurse Researchers: Protecting Human Subjects

Nursing research is a relatively small community in Navy medicine, with a total of 11 billets—three at Portsmouth, three at NMCS (see page 5), and the remainder assigned to the National Capital Area district (Walter Reed National Military Medi-



CDR Craig Cunningham

cal Center, Bethesda, Md.), Marine Corps Base Camp Pendleton, Calif., and USUHS.

Prior to the 1980s, Navy nursing research consisted almost entirely of review-

ing unpublished doctoral theses.

According to the Tri-Service Nursing Research Program, formal research endeavors of the Navy Nurse Corps date to 1982. The Navy identified the need for 11 billets in 1987.

“The mission of Navy Nursing is to support military relevant research and a major part of supporting military relevant research is the protection of human subjects” says CDR Craig Cunningham, Head of the Nursing Research & Consultation Services Dept. and an IRB Vice-Chair at the Naval Medical Center Portsmouth, Va.

In order to ensure that research is conducted at NMCP in a way that protects human subjects, the nursing research department initiates and manages collaborations with outside institutions, has instituted human subject protection training for the nurse residency program, advises and supports the Nursing Research and Standards Committee, and has instituted a consultation process for busy clinicians interested in engaging in research.

“One way we in Nursing Research support military relevant research is through collaborations with outside institutions,” says Cunningham.

Right now, Duke University, the University of Alabama, Yale, University of Virginia, Old Dominion University, University of Colorado, and

Eastern Virginia Medical School are among the outside institutions working with NMCP nurse researchers.

“Our role is to help nurses in graduate programs (usually Duty Under Instruction students) conduct their military relevant research here at NMCP and to do it safely. In order to conduct research here, Principle Investigators must be NMCP staff members. Therefore, we—Nursing Research—set up educational partnership agreements which allow us to support the students to do their projects here.

“We allow them time to develop their protocol, interact with the right people, and learn the skills they need.”

In the process, students learn the difference between research, evidence-based practice, and process improvement projects. Cunningham explains that students will ask: “I’m not sure this is research—do I need IRB oversight?”

“We help them draft the description of their projects to send to the IRB for determination of IRB oversight. We actually prefer that students submit their protocols to the IRB—because then they get a chance to learn and de-mystify what the IRB is all about.”

“Another way we support military relevant research is through partnering with the nurse residency program director,” says Cunningham.

A major component of the Naval nursing research at NMCP, Cunningham says, is an eight-week nurse residency program lecture series.

“We introduce them to the research process, evidence-based practices, process improvement—and make sure they complete their training from the Collaborative Institutional Training Initiative (CITI).

“We want them to participate in research. In order to do that, they have to know how to protect human subjects,” he says. “So far—we stood the program up a year and a half ago—we’ve had 60 new nurses go through the program.” The nurse residency program lecture series was developed

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Navy Nursing Research, San Diego

San Diego Nursing Research: “Driven by Navy Needs”

CDR Heather King, a nurse researcher assigned to NMCSO, deployed on the hospital ship Mercy (T-AH-19) for the Rim of the Pacific (RIMPAC) multinational exercise this summer, will interview medical staff members (physicians, nurses, and corpsmen) aboard ship on their experiences during humanitarian, disaster assistance, and civic assistance missions for an oral history project.



CDR Dennis Spence

participated in similar missions while deployed to Afghanistan, Iraq, Djibouti, and other locations.

CDR Dennis Spence, Regional Director of Nursing Research, for NAVMEDWEST and Chair of the NMCSO Institutional Review Board, says that the oral history is one of several nursing research priorities at NMCSO that are “driven by the Navy’s needs.”

“The mission of NMCSO’s Nursing Research Department is to conduct and facilitate the completion of high-quality, multidisciplinary, collaborative re- search and evidence-based practice projects by nurses and health care professionals throughout the region,” Spence says.

As at NMC Portsmouth, he says, NMCSO’s Nursing Research Department has three billets: a regional director, a department head, and a nurse researcher.

Spence said over the last five years the Nurse Corps has increased the number of billets for nurses assigned to earn their Ph.D. Upon completing the

When completed, the project will consist of a video archive of the interviews, which planners, educators, and staff members can use to improve planning of and individual readiness for future missions.

King and her team also plan to interview personnel who have

Ph.D., the nurse researcher usually is assigned to either NMC Portsmouth or NMCSO. Recently a new nurse researcher was assigned to Marine Corps Combat Development Command; Quantico, Va. Five NMCSO nurses will complete their Ph.D. work in 2015.

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Surgeon General VADM Matthew Nathan departs hospital ship Mercy during RIMPAC

“For the first time in a number of years the nurse researcher community will be fully manned. These new nurse researchers will have a diverse research skill set, including qualitative and survey methodologies experience, and expertise ranging from women’s health issues, to traumatic brain injury and post-traumatic brain injury.

“This will allow NMCSO to expand its research portfolio and competitiveness for research grants in areas that are aligned with the Navy Medicine research priorities.”

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Navy Nursing Research, Portsmouth

“Multiple Areas in Support of Warfighters”

(Continued from page 3)

through collaboration with the Chairman of NMCP's Nursing Research and Standards Committee (NRSC), which supports the Director of Nursing Services. The committee seeks to involve nurses in research: providing training in such areas as the IRB process, research ethics, consent process, among other areas. The NRSC also mentors nurses who are conducting research, asking them about their approaches to collecting data, and offering them opportunities to brief other nurses on their projects. Cunningham notes that having the nurse researchers answer questions from peers helps the program's whole team approach.

An important part of the nursing research program, Cunningham says, is “sitting down with the busy clinician—hence the term “consultation services”—to discuss his or her work, with the goal of developing ideas for protocols and sometimes, obtaining funding and staff to support research.

“Many of our clinicians want to engage in research but acknowledge that they don't really understand the process—even with the wonderful training opportunities that are provided by the clinical investigation department at NMCP.

“Many clinicians want a little more guidance to ensure that they are doing things correctly, such as protecting human subjects.”

Currently, the department is focused on multiple areas in support of warfighters, including work on PTSD and mild traumatic brain injury.

A current study, now in literature review, is related to military sexual trauma. However, the researcher conducting the literature review probably will leave and turn the data collection and/or the analysis over to someone else.

To ensure the stability, continuity, and protection of human subjects related to the work, it's essential to maintain the involvement of nursing research. “We respond to the continuing review, we help write up how we're doing, and we prepare presentations,” Cunningham says.

The nursing researchers who initiate the research and then move to other assignments help “expand



LCDR Vorachai Sribanditmongkol, NMCP Associate Dept. Head, Nursing Research, with CDR Cunningham

the footprint” of Navy nursing research, Cunningham says.

Some of the projects that the nursing research department at NMCP supports include: a “self-report” outcomes measure to evaluate the use of evidence-based mental health treatments; deployment factors in parenting stress; and the use of intrathecal morphine for post-operative pain.

One student that is being mentored by the nursing research department is working on a study on U.S. Navy women's experience with cervical cancer screening and follow-up care.

Currently, Nursing Research and the directorate of mental health at NMCP are seeking funding to establish a Center for Psycho-Bio-Behavioral Research, aimed at bringing together medicine, nursing, mental healthcare, and research.

The Center, Cunningham says, “will go a long way in supporting nursing, mental health, and medical research.”

“We're doing a lot of good things, and I think we're doing them right,” he says. We (NMCP) have in the past got a reputation for being very conservative, and I think that's good.

I want to get as many nurses involved in research as I can and I want them to do it safely.”

Navy Nursing Research, San Diego

Navy Nurses Offer “A Diverse Research Skill Set”

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In addition to developing research and evidence-based practice projects at NMCSO, Spence says the NMCSO Nursing Research Department focuses on mentoring and promoting scholarly activity throughout NAVMEDWEST. Over the last several years the department has mentored doctors and nurses stationed in Guam, Okinawa, Oak Harbor and Bremerton, Wash., and Lemoore, Calif. Spence also has served on several dissertation committees for nurses completing their Ph.D. at the University of San Diego.

As the Nursing Research regional director, he says, he acts as a mentor and resource for nurses' and physicians' scholarly activity—helping them write manuscripts, monitoring compliance with human subject research requirements, and overseeing evidence-based practice projects.



Hospital Ship Mercy tied up at San Diego prior to deployment for RIMPAC

“My experience as a researcher, relationships with academic institutions regionally and nationally, and with senior Navy leadership, and experience as IRB Chair are tremendous assets to the nurses and physicians I mentor.”

He explains that to make the mentoring process easier, the Nursing Research Department teamed with the TriService Nursing Research Program to develop online video podcasts on evidence-based practices, scientific writing, statistics, research

methodologies, and human subject research topics. Spence says the podcasts promote evidence-based practices and proper conduct of research by nurses, physicians, and other DoD health professionals (<http://www.usuhs.mil/tsnnp/Training/opportunities.php>).

The Nurse Research Department is collaborating with the NMCSO Bioskills & Simulation Training Center to develop the infrastructure to conduct multidisciplinary, collaborative simulation, bioskills and



NMCSO Nursing Research and a civilian training center will develop life-saving techniques using an MV-22 fuselage

human factors projects in the NAVMEDWEST region. He says the Center's activities will help fill gaps in knowledge and promote operational and clinical readiness for personnel in the region, for example, to prepare Navy and Marine Corps personnel for increased operational tempo in the Asia-Pacific region.

A major project of the collaboration is to bring the fuselage of an MV-22 Osprey tilt-rotor aircraft to the San Diego Strategic Operations Tactical Training Center to develop a training platform for tactical combat casualty care aboard the Osprey.

The adaptation of life-saving medical equipment and techniques to the Osprey platform should minimize the potential for emergencies during transport aboard the aircraft. This enhanced capability to safeguard casualties would be especially valuable during transits in the Pacific theater, Spence says.

Command Focus

NAMRU-3: A Strong Ethics Foundation for Life-Saving Research

The Navy established the U.S. Naval Medical Research Unit No. 3 (NAMRU-3) in 1946, building on the achievements of American scientists and technicians who worked with Egyptian physicians at the Abbassia Fever Hospital in Cairo under the auspices of the United States Typhus Commission. At the end of World War II, the Egyptian government invited the U. S. Navy to continue to collaborate with Egyptian scientists on studies of endemic tropical and subtropical diseases.



NAMRU-3's mission is to conduct infectious disease research, including evaluation of vaccines, therapeutic agents, diagnostic assays, and vector control measures. The lab also car-

ries out public health disease surveillance and outbreak-response assistance.

NAMRU-3 is engaged in research involving human subjects conducted in several countries across the United States Africa Command (AFRICOM), Central Command (CENTCOM), and European Command (EUCOM) areas of responsibility.

In 1989 NAMRU-3 became a World Health Organization (WHO) collaborating center for HIV/AIDS. DoD established a Global Emerging Infections System program in 1999 that expanded NAMRU-3's public health activities and upgraded research capability. In 2001 NAMRU-3 was recognized as a WHO Collaborating Center for Emerging and Re-Emerging Infectious Diseases. NAMRU-3 also serves as a WHO reference lab for influenza/H5 and meningitis in the Eastern Mediterranean Region.

NAMRU-3 is one of only two research institutions in North Africa with a functional Biosafety Level (BSL-3) laboratory.

The NAMRU-3 IRB office was established to coordinate and oversee the review and approval

process for the conduct of research and to assist the Commanding Officer (CO) in the discharge of his/her overall responsibility for the program. The CO is designated as the Signatory Official for granting final approval for research, and has overall responsibility for the conduct of the HRPP.

As the Signatory Official, the CO signs off on the initiation of research only after his review of the proposed research and documentation, which must provide solid verification of fulfillment of the requirement for scientific and ethics review.

NAMRU-3 human and animal research is subject to approval by the IRB and/or the Institutional Animal Care and Use Committee. NAMRU-3 HRPP activities can impact the Command's reputation as an overseas DoD laboratory.

Command HRPP performance builds on the efforts of all involved in design, review, approval, conduct, oversight, and monitoring of human research.

The strong scientific and ethical foundation of NAMRU-3 research is ensured through two-tiered reviews by the NAMRU-3 Scientific Review Board (SRB) and IRB. Collaborators also are encouraged to conduct their own ethical reviews in order to ensure that the research meets the scientific and ethics review requirements of the host countries.

The Command is particularly sensitive to the need to uphold the principle of respect for and protection of the rights of human subjects.

The Command requires strict adherence to the ethical principles and standards of responsible conduct by all staff members.

Careful selection of individuals who may serve as members of the SRB and IRB is a major factor in ensuring the quality of initial and continuing research review and oversight.

NAMRU-3 faces the challenge of ensuring that the research conducted has credible scientific value, meets research needs of collaborators and the requirement for military relevance, and complies with all applicable rules and regulations.

New Roles for Clemmons; Brown, Campbell, and May Join DON HRPP

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Human Research Protection Office at the University of Maryland School of Medicine.

A retired Navy Chief Hospital Corpsman and native of Baltimore, Clemmons served with the Marine Corps 3rd Force Service Support Group on Okinawa, Japan and deployed for Operations Desert Shield and Desert Storm.

Tamika Brown and Suzanne May, federal employees, and Adrienne Campbell, with Avian LLC, have joined ONR's Research Protection Division. Brown, a native of Chicago, has taken the position of DON HRPP Human Research Protection Specialist (Training), after serving as a research health science specialist at the Veterans Administration in Durham, N.C.



Tamika Brown

During her tenure at the VA Brown managed the planning and implementation of several national behavioral research studies involving mental health. Brown earned a B.S. in biochemistry and cellular and molecular biology at the University of Tennessee and an M.S. in environmental assessment at North Carolina State University. During her senior year at Tennessee she was awarded a National Institutes of Health fellowship for study at the University of Massachusetts Medical School.

May has joined DON HRPP's ONR office as a Human Research Protection Specialist. She comes to DON HRPP after serving as the regulatory affairs officer at the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) in Washington, DC. In this role, she provided oversight of the human subjects research studies conducted by

the Foundation in 14 countries; ensuring compliance with all applicable federal and international regulations and local laws.



Suzanne May

Previously she was an Assistant Director of Accreditation at the Association for the Accreditation of Human Research Protection Programs (AAHRPP), and prior to that was an IRB program manager with the Inova Health System in Falls Church, VA. She holds a Master of Public Health from Emory University and a B.A. from Earlham College.

Campbell, joining DON HRPP as a Human Research Compliance Specialist, holds a B.S. in Biology from Lincoln University.

Originally from Washington, D.C., she comes to DON HRPP after serving as a regulatory affairs coordinator with the Henry M. Jackson Foundation, at the Walter Reed National Military Medical Center, Bethesda, Md. In that role, she



Adrienne Campbell

provided regulatory support and guidance to clinical research staff members and senior investigators, and managed preparation of research protocols for IRB submission.

Previously, she worked for the University of Maryland-Baltimore as an IRB analyst, and prior to that, as a regulatory affairs specialist for the U.S. Military Cancer Institute at Walter Reed.

Reporting Requirements

Requirements for reporting events of non-compliance with human research protections policies are based on the following regulations and instructions: Title 32 Code of Federal Regulations Part 219 (32 CFR 219), known as the “Common Rule”, Department of Defense Instruction 3216.02 (DoDI 3216.02), and the Navy’s HRPP instruction, Secretary of the Navy Instruction 3900.39D (SECNAVINST 3900.39D).

All three differ to some extent on the kinds of events to be reported, to whom those reports are to be made, and the timeliness of reporting.

32 CFR 219 and DoDI 3216.02 stipulate rough timeframes for reporting (“prompt” and “in a timely manner,” respectively), while the SECNAVINST does not. The DoDI refers to “substantiated allegations” as reportable. However, the Navy instruction is much more detailed on reporting requirements. Events to be reported, and to whom, vary with the research role.

The SECNAVINST requires investigators to report to the IRB unanticipated problems involving risks to subjects or others (UPIRTSOs); serious adverse events (SAEs); serious or continuing noncompliance with human subject protection regulations and IRB requirements; and protocol deviations.

IRBs must report to commanding officers all suspensions or terminations of previously approved research protocols; the initiation of investigations of

alleged non-compliance with human subject protections; any UPIRTSOs or serious adverse events; and all audits, investigations, or inspections of the HRPP conducted by an outside entity.

COs are required to report the following to the DON HRPP Director and appropriate sponsor(s): UPIRTSOs or serious adverse events; all suspensions or terminations of previously approved research protocols; and the initiation of all investigations of non-compliance with human subject protections.

COs also must report the results of all investigations of noncompliance with human subject protections, regardless of the findings; the initiation of all investigations of research misconduct and results of those investigations, regardless of the findings; and all audits, investigations, or inspections of DON- supported research protocols. DON HRPP then reports to the Navy Surgeon General. The SG is required to report all findings of serious noncompliance with human subject protections and, as appropriate, UPIRTSOs or serious adverse events to the Assistant Secretary of Defense for Research & Engineering via the Assistant Secretary of the Navy for Research, Development & Acquisitions and the Under Secretary of the Navy.

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